

**DETAILED ACTION**

1. The following is in response to the amendment filed September 14, 2011.
2. Claims 1-3, 8-11, 13, and 22-31 are currently pending.

***Claim Objections***

3. The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not). Claims 25-31 were previously cancelled (see amendments filed 1/15/2010 and 7/31/09).

Misnumbered claims 25-31 have been renumbered 59-65.

***Terminal Disclaimer***

4. The terminal disclaimer filed on December 4, 2008 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of US Application No. 11/662,032 has been reviewed and is NOT accepted.

5. The terminal disclaimer does not comply with 37 CFR 1.321(b) and/or (c) because:

The disclaimer fee in accordance with 37 CFR 1.20(d) has not been submitted, nor is there any authorization in the application file to charge a specified Deposit Account or credit card.

6. However, it is noted the double patenting rejection set forth in the July 22, 2008 Office Action has been withdrawn in view of the amendments made to the claims in each Application, which are now patentably distinct.

***Claim Rejections - 35 USC § 112***

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 1-3, 8-11, 13, and 22-31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
9. Claim 1 recites the limitation "the petals" in line 11. There is insufficient antecedent basis for this limitation in the claim.

***Claim Rejections - 35 USC § 102***

10. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
11. Claims 1 and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Ewerhardt et al. (US 1,950,788). Regarding claim 1, Ewerhardt et al. disclose a diagnostic device for pathologies of naturally occurring tubular anatomical structures comprising: a tubular elongated structure (10) developing between a proximal end and a distal end and being adapted to be inserted in the tubular anatomical structure, wherein the tubular elongated structure comprises an inner tube (15) and an outer tube (10) adapted to internally receive the inner tube. The device further comprises means for locally dilating (12) the walls of the tubular anatomical structure being associated with the distal end of said elongated structure. The means for locally dilating comprises a plurality of petals (12) arranged such that a first end thereof is associated to the distal end of the elongated tubular structure and the petals are adapted to assume at least one open configuration (Fig 2) and one closed configuration (Fig 1). The petals are movable between a closed position (Fig. 1), wherein the petals overlap each other for introduction of the

device, and at least one open position (Fig. 2) for the viewing and evaluation of the pathology. Control means (21) are associated to the proximal end of the elongated structure, said control means being operatively connected to said means for locally dilating in order to move them between the closed position and the open position, and vice versa (col. 3, In. 47-51). The petals (12) are attached to the outer tube (10) to form one piece and the petals further coupled with a portion of the inner tube (15) to form a unidirectional guide adapted to close or open the petals in response to the translation of the inner tube relative to the outer tube (col. 3, ll 15-19).

Regarding claim 22, Ewerhardt et al. disclose each petal (12) comprises a longitudinally extending rib (17) and wherein said inner tube (15) comprises a distal flange (16) provided with openings adapted to couple with respective ribs (17) of said petals (col. 2, In. 105-120).

***Claim Rejections - 35 USC § 103***

12. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

13. Claim 2 and 3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ewerhardt et al. (US 1,950,788), as applied to claim 1 above, in view of Wallace (US 2,621,651). Ewerhardt et al. disclose the invention substantially as claimed, as shown above. However, Ewerhardt et al. fail to disclose a means of viewing adapted to be associated with the elongated tubular structure and to reach the tract of the tubular anatomical structure. Wallace et al. disclose a dilating instrument locally dilating tubular anatomical structures, the dilator comprising an elongated means of viewing (40) associated with a hollow elongated tubular member for viewing the dilated area. It would have been obvious to one of ordinary skill in the art to modify the dilation tool of Ewerhardt et al. to comprise a means of viewing associated with

the hollow elongated tubular member as suggested by Wallace et al. to allow the surgeon to view the surgical site.

14. Claims 8 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ewerhardt et al. (US 1,950,788), as applied to claim 1 above, in view of Bertolero et al. (US 2005/0159645). Ewerhardt et al. disclose the invention substantially as claimed, as shown above. However, Ewerhardt et al. fail to disclose a petal and outer surface of the outer tube comprise at least one detection element or marker. Bertolero et al. disclose a detection element or marker on an outer sheath (paragraph 8) for determining the location in the body. It would have been obvious to one of skill in the art to modify Ewerhardt such that a detection element or radiopaque marker was provided on the outer tube and/or on at least one petal to allow the location of the device in the body to be determined.

15. Claims 9-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ewerhardt et al. (US 1,950,788), as applied to claim 1 above, in view of Pena (US 5,178,133). Ewerhardt et al. disclose the invention substantially as claimed, as shown above. However, Ewerhardt et al. fail to disclose a continuous membrane. Pena discloses a means for locally dilating (12) comprising a continuous transparent elastic membrane (34) externally covering dilating arms (12) for allowing the surgeon optimal viewing of the surgical field (see abstract). It would have been obvious to one of ordinary skill in the art to modify Ewerhardt et al. to include a continuous transparent elastic membrane externally covering the petals to evenly dilate the surrounding tissue in the surgical field as suggested by Pena. Ewerhardt et al. in view of Pena disclose the membrane external to the petals when the petals are overlapping in the closed position.

16. Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ewerhardt et al. (US 1,950,788), as applied to claim 1 above. Ewerhardt et al. disclose the invention substantially as claimed, as shown above. However, Ewerhardt et al. fail to disclose the rib (17) has a T-shaped cross-section and the openings have a C-shaped cross-section suitable to couple with the cross-section of a respective rib. It would have been an obvious matter of design choice to give the rib a T-shaped cross section and the openings of the inner tube of the distal flange a C-shaped cross section, since applicant has not disclosed that the particular coupling solves any stated problem or is for any particular purpose and it appears that the invention would perform equally well with the ribs and the openings having any shaped cross-sections which fit together.

17. Claims 24 and 59 (previously presented as claim 25) are rejected under 35 U.S.C. 103(a) as being unpatentable over Ewerhardt et al. (US 1,950,788), as applied to claim 1 above, in view of Sijp (DE 19828099 A1). Ewerhardt et al. disclose the invention substantially as claimed, as shown above. However, Ewerhardt et al. fail to disclose a holding body at the proximal end of the outer tube. Sijp discloses a device for dilating a tubular anatomical structure comprising an elongated structure, petals for locally dilating the walls of the anatomical structure, the elongated structure comprises an inner tube (10) and an outer tube (1) adapted to internally receive said inner tube, said inner tube and said outer tube being suitable to translate relatively to each other to open or close said petals (Fig. 4-5). Sijp discloses a holding body (6) arranged at the proximal end of an outer tube and a holding body (6) arranged at the proximal end of said inner tube, wherein the holding bodies are in the shape of a handle. It would have been obvious to one of ordinary skill in the art to one of ordinary skill in the art to substitute the elongated tubular structure of Ewerhardt et al. with the elongated tubular structure including the

holding members of Sijp in order to achieve the same predictable result of opening and closing the petals through relative movement of the inner and outer tubes.

18. Claims 60-63 (previously presented as claims 26-29) are rejected under 35 U.S.C. 103(a) as being unpatentable over Ewerhardt et al. (US 1,950,788), as applied to claim 1 above, in view of Nady-Mohamed (US 5,353,784). Ewerhardt et al. disclose the invention substantially as claimed, as shown above. However, Ewerhardt et al. fail to disclose a holding body at the proximal end of the outer tube and fail to disclose a further holding body at the proximal end of the outer tube that comprises first and second portions rotatable relative to one another. Nady-Mohamed discloses a device for dilating a tubular anatomical structure (Figs 1-2) comprising an elongated structure, petals for locally dilating the walls of the anatomical structure, the elongated structure comprises an inner tube (11) and an outer tube (10) adapted to internally receive said inner tube, said inner tube and said outer tube being suitable to translate relative to each other to open or close said petals (Fig. 5). Nady-Mohamed discloses a holding body (18) arranged at the proximal end of the inner tube and a holding body arranged at the proximal end of said outer tube. The outer tube holding body comprises a trigger having a first portion (41) and second portion (42) rotatable relative to one another to cause translation of the inner tube relative to the outer tube and comprises a at least one rib (45) corresponding to an intermediate open configuration of the device when the device is placed in such a configuration. It would have been obvious to one of ordinary skill in the art to one of ordinary skill in the art to substitute the elongated tubular structure of Ewerhardt et al. with the elongated tubular structure including the holding members of Nady-Mohamed in order to achieve the same predictable result of opening and closing the petals through relative movement of the inner and outer tubes.

19. Claim 64 (previously presented as claim 30) is rejected under 35 U.S.C. 103(a) as being unpatentable over Ewerhardt et al. (US 1,950,788) and Nady-Mohamed (US 5,353,784), as applied to claim 63 above (previously presented as claim 29), in view of Williamson et al. (US 5,972,004). Ewerhardt et al. and Nady-Mohamed disclose the invention substantially as claimed, as shown above. However, the combination of Ewerhardt et al. and Nady-Mohamed fails to disclose the trigger comprises a toothed area suitable to couple with a proximal grooved length of the inner tube. Williamson et al. teach a trigger (212) comprising a toothed area (216) suitable to couple with a proximal grooved length (218) of the inner tube for advancing a cutter distally (col 16, ll 27-30). It would have been obvious to modify the combination of Ewerhardt et al. and Nady-Mohamed such that the coupling between the trigger and inner tube was substituted with the trigger "gear" and inner member "rack" configuration to achieve the same predictable result of a trigger member causing a tube to move distally. Substitution of one known element for another known element providing the same function to yield predictable results would have been obvious to one of ordinary skill in the art at the time of the invention.

20. Claim 65 (previously presented as claim 31) is rejected under 35 U.S.C. 103(a) as being unpatentable over Ewerhardt et al. (US 1,950,788) and Nady-Mohamed (US 5,353,784), as applied to claim 63 above (previously presented as claim 29), in view of Lapkin et al. (US 3,667,474). Ewerhardt et al. and Nady-Mohamed disclose the invention substantially as claimed, as shown above. However, the combination of Ewerhardt et al. and Nady-Mohamed fails to disclose an elastic means biasing the trigger to a resting position. Lapkin et al. teach an elastic means (30) interposed between a holding body (25) and a trigger member (26) for returning the inner member and holding members to their original positions. It would have been obvious to modify the combination of Ewerhardt et al. and Nady-Mohamed such that an elastic

member was provided to return the members to their initial positions through an elastic force, as taught by Lapkin et al.

### ***Response to Arguments***

21. Applicant's arguments filed September 14, 2011 have been fully considered but they are not persuasive. Applicant argues Ewerhardt does not disclose the petals are formed as one piece with the outer tube. The examiner respectfully disagrees and notes Ewerhardt states the hinge may be integrally formed with the petals (12) and outer tube (10) and the connection between the petals, hinge, and outer tube forms a single piece since they are not separable. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the petals integrally formed with the outer tube to provide a non-traumatic continuously smooth transition from the outer tube to the petals) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

### ***Conclusion***

22. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period



will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

23. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Katherine Dowe whose telephone number is (571) 272-3201. The examiner can normally be reached Monday through Friday, 8:30am – 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, ***please contact the examiner's supervisor, Gary Jackson, at (571) 272-4697***. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

***If there are any inquiries that are not being addressed by first contacting the Examiner or the Supervisor, you may send an email inquiry to***

TC3700\_Workgroup\_D\_Inquiries@uspto.gov.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Katherine Dowe  
December 2, 2011

/Katherine M Dowe/  
Examiner, Art Unit 3734

/Gary Jackson/  
Supervisory Patent Examiner  
Art Unit 3734